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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/769,790	02/03/2004	Arie Luijck Visser	3560-0136P	9240
2292 7590 12/31/2007 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER COLQUITT, AARON BRUCE				
ART UNIT		PAPER NUMBER		
3735				
NOTIFICATION DATE		DELIVERY MODE		
12/31/2007		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary

Application No.

10/769,790

Applicant(s)

VISSCHER ET AL.

Examiner

AARON B. COLQUITT

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- Paper No(s) Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s) Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. This action is in response to the amendment filed on September 10, 2007. The examiner acknowledges the certified copy of European Priority document and the amendments of claims 1-22, the abstract, and the specification.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-11, 13, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6048300 to Thornton et al. (Thornton '300')

In Reference To Claims 1-11, 13, and 22

Thornton '300' teaches a limit stop mechanism in Fig. 7 that comprises a stack of washers (160) that have tang (162) and a central bore (164, Fig 8). The washers (160) are stacked on the switch lever, (54) which is rotatably (pivot) mounted on the bearing sleeve of the shaft (122). The lever (54, 56) is comprises a mechanism (90) that has a slider block (148) made of a low friction material such as UHMW (nontransparent) plastic (col. 9, lines 40-45). The lever (54) has a lever arm (168), which engages the tang 162a of the lower most washer 160a (first position). An upper stop cap (170) is fixed to the upper end of the shaft (122) and has an overhanging tang, which engages the tang (notch 162) of the uppermost washer (160b) (second position).

As the shaft (122) rotates the tangs (162) engage one another. Tang (162a) engages the lever arm (168) of the switch lever (54) to rotate against a spring force until one of a pair of microswitches (174) is operated (third position). Each microswitch (174) transmits a signal to the afterloader control system electronics to indicate that the wire (W fig. 10) has reached the limit of its travel in that direction.

The stop positions for advancing and retracting the radioactive wire (W) can be adjusted for any given or desired wire length by varying the number of washers (160) on the shaft and by adjusting the angular position of the tang on the upper stop cap (170). (Column 10 Lines 4-31).

Furthermore a home sensor unit (114) precisely locates a distal tip of an active sourcewire. The home sensor unit may include an optical, mechanical (lever), or magnetic sensor which produces an output to the afterloader control system when the distal tip passes the home sensor unit either upon extension or retraction. The amount of wire extended can be measured and the determination of the status of the wire can be made (col. 7, lines 5-15). A lever element similar to that of (54) is interpreted as being the mechanical sensor (114). The lever element located at (114) would be capable of determining the location of the distal tip of an active sourcewire in a lumen using the same mechanisms as the prior addressed lever element (54).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claim(s) 12, 14, and 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6048300 to Thornton '300' in view of US 5957829 to Thornton '829'.

In Reference To Claims 12, 14, and 16-21

Thornton '300' teaches all the limitations of the first claim but fails to disclose the particular emission source type and sourcewire types.

In '829' Thornton teaches an after loader that is used to position a sourcewire in a predetermined location of a lumen. The sourcewire is formed of a nickel-titanium alloy, and the second segment of the wire can be made of a ferromagnetic ball. A Hall Effect sensor is configured to sense a variation in magnetic flux caused by the presence of the second segment of the source wire in a predetermined position in the path of the sourcewire (Column 2 Lines 36-58). The wire drives an optical encoder (31) that is used

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for positioning of the wire when its distal tip (24) passes by the prescribed position within the afterloader (Column 4 Lines 1-5).

Other embodiments and variations of the source and sourcewire would still fit the limitations of the scope of the invention.

It would have been obvious to one of ordinary skill in the art at the time of the invention was made to combine the teachings of Thornton '300' wherein there is an active but undefined sourcewire type with a variety of sourcewire types similar to that of Thornton '829' to achieve various combinations of radioactive sources and source wires that is detectable by a hall sensor in order to have a device that can accommodate the multiple types of energy sources and source wires that may be available to a user.

7. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Thornton '300' in view of US 5997462 to Loffler (Loffler).

In Reference To Claim 15

Thornton '300' teaches the limitations of the first claim but fails to disclose teachings about an energy emitting source that is an X-ray source.

Loffler, however, teaches a radiation device that uses X-ray radiography or fluoroscopy that cooperates with a receiver for imagine opaque materials in the body of a patient. The radiation device is used to exactly position the catheter and the source relative to the location of the lesion.

It would have been obvious to one of ordinary skill in the art at the time of the invention was made to use a device similar to that of Thornton '300' with a miniature X-ray

source similar to that of Loffler to provide for a sensing device that can detect a multitude of energy emitting sources.

Response to Arguments

8. Applicant's arguments, see pages (8-10), filed September 10, 2007, with respect to the rejection(s) of claim(s) 1-11, 13, 16 and 22 under 102(b) to Thornton'300 have been considered but they are not persuasive.

Thornton'300 teaches a home sensor unit that includes an optical sensor that can identify the amount of extension of the wire and where the distal tip of the sensor is located. The lever element (86) determines the amount of extension that is allowed by the wire and is adjustable. The home sensor unit located near the guidance channel may include a mechanical sensor that enables the extended amount of wire to be measured. A device similar to that of the lever element can be used to identify where the location of the distal end of the wire source is when compared to a prior location of a guidewire.

9. Applicant's arguments, see page 10, filed September 10, 2007, with respect to the rejection(s) of claim(s) 12 and 14-21 under 103(a) to Thornton'300 in view of Thornton'829 have been fully considered and are not persuasive.

The sourcewire of Thornton'829 is designed to be configured by an afterloader similar to that of Thornton'300 to controllably position the source wire within a catheter lumen in a body and therefore would read on the claims 12 and 14-21 under 103(a).

10. Applicant's arguments, see page 10, filed September 10, 2007, with respect to the rejection(s) of claim(s) 15 under 103(a) to Thornton'300 in view of Loffler'462 have been fully considered and are not persuasive. Loffler'462 teaches the use of markers in the form of X-ray radiography and fluoroscopy devices to assist the physician in determining the position of the source within the centering catheter by viewing in the markers and the source and therefore read on claim 15 under 103(a) as a replacement of the sourcewire of Thornton'300 as an alternate energy emitting source for determining the distal end of a sourcewire.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
12. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **AARON B. COLQUITT** whose telephone number is

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(571)270-1991. The examiner can normally be reached on Monday-Friday 7:30 - 5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735

/A. B. C./
Examiner, Art Unit 3735
12/27/2007